

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2016-0003; NIOSH 057-A]

Draft Criteria for a Recommended Standard: Occupational Exposure to 1-Bromopropane (1-BP); Notice of public meeting; Availability of draft document for comment.

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting and availability of draft document for public comment.

SUMMARY: On September 16, 2009, the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC) announced in the Federal Register https://www.gpo.gov/fdsys/pkg/FR-2009-09-16/pdf/E9-22297.pdf plans to evaluate the scientific data on 1-bromopropane (1-BP) and to issue its findings on the potential health risks. A draft document entitled, Criteria

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for a Recommended Standard: Occupational Exposure to 1-Bromopropane (1-BP), has been developed which contains an assessment of toxicological data and provides recommendations for the safe handling of 1-BP-containing materials. NIOSH is seeking comments on the draft document and plans to have a public meeting to discuss the document. The draft document and instructions for submitting comments can be found at www.regulations.gov.

DATES: The public meeting will be held on March 30, 2016, 9:00 a.m.-3:00 p.m. Eastern Time, or after the last public commenter has spoken, whichever occurs first. Comments must be received by April 29, 2016.

ADDRESSES: The public meeting will be held at the NIOSH/CDC Robert A. Taft Laboratories, Auditorium, 1150 Tusculum Avenue, Cincinnati, Ohio 45226.

FOR FURTHER INFORMATION CONTACT: G. Scott Dotson, NIOSH,
Education and Information Division, Robert A. Taft
Laboratories, 1090 Tusculum Avenue, Cincinnati, OH 45226,
(513) 533-8540 (not a toll free number).

SUPPLEMENTARY INFORMATION:

- I. Background: On September 16, 2009, the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC) announced in the Federal Register plans to evaluate the scientific data on 1-bromopropane (1-BP) and to issue its findings on the potential health risks. The results of this evaluation are presented in the draft document, Criteria for a Recommended Standard:

 Occupational Exposure to 1-Bromopropane (1-BP). The purpose of the public meeting and public comment period is to obtain comments on the draft document.

 Special emphasis will be placed on the following:
- Whether the health hazard identification, risk
 estimation, and discussion of health effects of 1-BP
 are a reasonable reflection of the current
 understanding of the scientific literature;
- Identifying workplaces and occupations where exposure to 1-BP may occur;

- Identifying studies on health effects associated with occupational exposure to 1-BP that were not identified in the draft;
- Identifying current strategies for controlling or preventing exposure to 1-BP (e.g., engineering controls, work practices, personal protective equipment);
- Identifying current exposure measurement methods and challenges in measuring workplace exposures to 1-BP;
 and
- Identifying areas for future collaborative efforts (e.g., research, communication, development of exposure measurement and control strategies).

As part of the review of this draft criteria document, reviewers are asked to address the following critical questions:

(1) Does the draft criteria document accurately identify and characterize the health hazards of occupational exposures to 1-BP based on the current understanding of the scientific literature? Please identify any

additional relevant literature that NIOSH should consider when developing its recommendations.

Is the risk estimation for 1-BP presented in the draft criteria document a reasonable reflection of the current understanding of the scientific literature? Please describe any changes in the risk estimation that NIOSH should consider and provide supporting scientific literature.

- (2) Are there other risk assessment methods or health endpoints that NIOSH should consider for estimating risks of 1-BP? Please provide supporting scientific literature or other evidence to support your recommendations.
- (3) In this draft criteria document, NIOSH proposes a recommended exposure limit (REL) to prevent a risk of one excess cancer in 1000 workers exposed to 1-BP for a 45-year working lifetime. During development of the draft criteria document, NIOSH also considered setting the REL at a level to prevent 1 excess cancer in 10,000 workers for a 45-year working lifetime. Please comment on the excess cancer risk level and resulting REL for 1-BP.

- (4) Is the relationship between exposure to 1-BP and biological activity (toxicity) accurately presented in the draft criteria document?
- (5) Are the recommended strategies for controlling or preventing exposure to 1-BP (e.g., engineering controls, work practices, personal protective equipment) reasonable and technically feasible?
- (6) Are there other techniques or technologies capable of controlling workplace exposures to 1-BP that should be discussed in the draft criteria document?
- (7) Are the exposure measurement methods and the associated challenges in measuring workplace exposures to 1-BP adequately addressed in the draft criteria document?
- (8) Are there medical screening and surveillance measures, such as specific diagnostic tests, guidelines, and metrics, that should be implemented for workers expected of being exposed to 1-BP that are not discussed in the draft criteria document?
- (9) Are there biological indices or metrics that should be used to aid in the interpretation of biomonitoring data for 1-BP? What is the most appropriate biomarker that can confirm and quantify occupational exposures to 1-BP?

- (10) Should acute exposure recommendations, such as a short term exposure limit (STEL), be derived for 1-BP? If so, what data support the development of the STEL?
- (11) NIOSH provided Globally Harmonized System (GHS) of Classification and Labelling of Chemicals designations for health endpoints evaluated in the criteria document. Please comment on the utility of these classifications for hazard communication. Are these classifications helpful for employers?
- II. Public Meeting: NIOSH will hold a public meeting on the draft document Criteria for a Recommended Standard:

 Occupational Exposure to 1-Bromopropane (1-BP) to allow commenters to provide oral comments on the draft document, to inform NIOSH about additional relevant data or information, and to ask questions on the draft document and NIOSH recommendations.

This meeting is open to the public. Attendance is limited only by the space available. The meeting room accommodates 100 people. The meeting will be open to a limited number of participants through a conference call phone number and Webcast live on the Internet.

Notification of intent to attend the meeting, for in-person and remote participation, must be made to the NIOSH Docket Office, at nioshdocket@cdc.gov, (513)533-8611, no later than March 16, 2016. Priority for attendance will be given to those providing oral comments. Other requests to attend the meeting will then be accommodated on a first-come, first-served basis.

Registration is required for in-person attendance and remote participation. Because this meeting is being held at a federal site, pre-registration is required on or before March 16, 2016 and a government-issued photo ID (driver's license, military ID or passport) will be required to obtain entrance to the facility. There will be an airport-type security check. Non-US citizens need to register by February 24, 2016 to allow sufficient time for mandatory facility security clearance procedures to be completed. This information will be transmitted to the CDC Security Office for approval. An email confirming registration will be sent from NIOSH for both in-person participation and audio conferencing participation.

Oral comments will be permitted for 15 minutes. If additional time becomes available, presenters will be notified. All requests to present should contain the name, address, telephone number, and relevant business affiliations of the presenter, topic of the presentation, whether you will be presenting in person or by phone, and the approximate time requested for the presentation. An email confirming registration will be sent from the NIOSH Docket Office and will include details needed to participate. Oral comments given at the meeting will be recorded and included in the docket.

After reviewing the requests for presentations, NIOSH will notify the presenter when his/her presentation is scheduled. If a participant is not in attendance when his/her presentation is scheduled to begin, the remaining participants will be heard in order. After the last scheduled speaker is heard, participants who missed their assigned times may be allowed to speak, limited by time available.

Attendees who wish to speak but did not submit a request for the opportunity to make a presentation may be given this opportunity after the scheduled speakers are heard, at

the discretion of the presiding officer and limited by time available.

You may submit comments, identified by CDC 2016-0003 and NIOSH 057-A, by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov.

 Follow the instructions for submitting comments.
- Mail: National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS
 C-34, Cincinnati, Ohio 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2016-0003; NIOSH 057-A]. All relevant comments received will be posted without change to www.regulations.gov including any personal information provided. All information will be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, Ohio 45226.

Non-U.S. Citizens: Because of CDC Security Regulations, any non-U.S. citizen wishing to attend this meeting must provide the following information in writing to the NIOSH Docket Officer at the address below no later than February 24, 2016.

Name:

Gender:

Date of Birth:

Place of Birth (city, province, state, country):

Citizenship:

Passport Number:

Date of Passport Issue:

Date of Passport Expiration:

Type of Visa:

U.S. Naturalization Number (if a naturalized citizen):

U.S. Naturalization Date (if a naturalized citizen):

Visitor's Organization:

Organization Address:

Organization Telephone Number:

Visitor's Position/Title within the Organization:

This information will be transmitted to the CDC Security
Office for approval. Visitors will be notified as soon as
approval has been obtained.

Public Review

The external review of the draft document has been (1)

developed in accordance with Office of Management and

Budget (OMB) guidelines, (2) is consistent with NIOSH peer

review practice, and (3) is meant to ensure that credible

and appropriate science is reflected within the draft

document.

Dated: February 4, 2016.

John Howard,

Director, National Institute for Occupational Safety and

Health, Centers for Disease Control and Prevention.

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